

REMARKS

Claims 1, 3-7, and 9-17 are pending in this application. Claims 1, 3-4, and 9-12 have been amended and claims 2 and 8 have been canceled without acquiescence and without prejudice. Claims 18-38 have been canceled without prejudice and without acquiescence, as they are drawn to a non-elected invention. Applicants retain the right to file divisional and/or continuation applications on any canceled subject matter. No new matter has been added.

The outstanding issues are as follows:

- The Specification is objected under 37 CFR 1.821(d) for failing to disclose SEQ ID NOS for the nucleic acid sequences disclosed on pages 41 and 42.
- Claims 1-17 have been rejected under 35 USC 112, first paragraph for allegedly containing subject matter which was not described in such a way as to enable one skilled in the art.
- Claims 1-17 have been rejected under 35 USC 112, first paragraph for allegedly containing subject matter which was not described in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.
- Claims 1-17 have been rejected under 35 USC 102(e) as allegedly being anticipated by US Patent 6,420,526 or US Patent 6,504,010.

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the remarks contained herein.

I. Specification Objection

The Examiner has objected to the specification under 37 CFR 1.821 (d) for failing to disclose SEQ ID NOS for the nucleic acid sequences disclosed on pages 41 and 42. Applicants are confused by this objection. A sequence listing was filed with the application containing all the sequences. Yet further, upon review of pages 41 and 42, it appears that all sequences are identified by SEQ ID NOS. Applicants request that the Examiner identify the specific sequences by paragraph number.

II. 35 U.S.C. §112, first paragraph

A. Enablement

Claims 1-17 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in such a way as to enable one of skill in the art to make and/or use the invention. The Examiner indicates that the specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation. Applicants respectfully traverse.

Applicants remind the Examiner that an invention need not be reduced to practice prior to filing (*Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987)). Yet further, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Applicants refer the Examiner to the enclosed Declaration by Marie-Claude Gingras and to Bouchon et al., Nature 410:1103-1107, 2001. Applicants assert that Bouchon et al utilized the teachings of the present invention to show that a soluble TREM-1 receptor inhibits cell functions that are activated by TREM-1 (for example, reduced the activity of TREM-1/DAP12 complex, and reduced inflammation). Thus, the soluble TREM-1 receptor of Bouchon et al. was acting as a competitive inhibitor, as described by the present application.

Applicants assert that the quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether undue

experimentation is required to make and use the invention. An extended period of experimentation may not necessarily be undue if sufficient direction or guidance is provided. Applicants assert that the methods outlined in the specification provide skilled artisans sufficient directions to enable the modulation of the immune response by administering a compound that decreases the activity of DAP12/TREM-1 complex, as illustrated by Bouchon et al. *In re Colianni*, 561 F.2d 220, 224, 195 U.S.P.Q. 150, 153 (CCPA 1977). Thus, the amount of experimentation is permissible because it is merely routine and the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 5F.2d 731, 737, 8 U.S.P.Q.2D 1400, 1404 in (Fed. Cir. 1988). In light of the data presented by Bouchon et al., Applicants assert that the present invention is enabled since one of skill in the art was able to practice the invention without undue experimentation.

Yet further, Applicants are confused by the statements made by the Examiner on page 4 of the Office action. It appears that the Examiner is requiring human trials as the only sufficient support for what the Examiner perceives is enablement of the claims. This is an absolutely improper standard. Although it is expected that pharmaceutical inventions will necessitate further research and development, clinical testing is not required to obtain a patent. *In re Brana*, 51 F.3d 1560, 1569 (Fed. Cir. 1995). Applicants are not required to perform FDA-type testing on humans in order to obtain a patent. The Examiner in this instance appears to be confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval for marketing drugs. *Id. at 1568*.

We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans.

Id. at 1667, citing In re Krimmel, 292 F.2d 948, 952 (CCPA 1961).

In light of the above arguments, Applicants assert that the claims are enabled and respectfully request that the rejection be withdrawn.

B. Written Description

Claims 1-17 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in such a way as to convey to one of skill in the art that the inventors had possession of the claimed invention.

Applicants assert that the description of the function of the compound provides sufficient written description. *See In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973). Techniques in molecular biology and protein chemistry are, and were at the time of the application, well known and understood in the art. Applicants assert that one of skill in the art would be able to follow the guidelines established in the specification to produce compounds that would result in the desired function. For example, the Specification in paragraphs [0069]-[0081] provides guidelines that are used to produce biological function equivalents of SEQ. ID. NO. 2.

In view of the above arguments, Applicants respectfully request that the rejection be withdrawn.

III. 35 U.S.C. § 102

Claims 1-17 are rejected under 35 U.S.C. § 102(e) as being anticipated by US patent 6,420,526 or US Patent 6,504,010. Applicants respectfully traverse.

Applicants did not receive the attached sequence alignment mentioned by the Examiner. SEQ. ID. NO. 2 of the present application is 150 amino acids in length compared to 234 amino acids in length of SEQ. ID. NO. 478 and 1825. Applicants request that these alignments be forwarded to the undersigned. In the meantime, Applicants note that from amino acid 137 to amino acid 150, there is very little similarity between SEQ. ID. NO. 2 and SEQ. ID. NO. 478 or 182.

Applicants remind the Examiner that in order to anticipate a claim, the reference must teach each and every element as set forth in the claim. *Verdegaal Bros. V. Union Oil Col. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In order to advance prosecution of the present application, claims 1-11 have been amended without prejudice and without acquiescence. Independent claims 1 and 7 are drawn

to administering a compound that is a competitive inhibitor of the ligand to TREM-1 to decrease the activity of DAP12/TREM-1 thereby resulting in a decrease in myeloid cell activation and/or an inflammatory response. Applicants assert that at best '526 teaches a sequence similar to TREM-1 or SEQ. ID. NO. 1 that may be involved in the activation of neutrophils, however, it does not teach nor does it make inherent that competitively inhibiting the ligand for TREM-1 or SEQ. ID. NO. 1 would result in a decrease in myeloid cell activation. Applicants assert that '526 teaches that the polynucleotides and polypeptides are useful as reagents for diagnostic procedures (See column 139, lines 21-25); useful in the expansion of stem cells and progenitors cells (See column 140 lines 1-2); and useful in the differentiation and/or proliferation of various cell types (See column 140, lines 3). The other item mentioned in '526 is that the proteins, as well as, antibodies directed against the proteins may be useful as tumor markers and/or immunotherapy targets. No where in the application can the Applicants find a teaching that a competitive inhibitor for SEQ. ID. NO. 478 is used nor a teaching that would make an inhibitor of the ligand to TREM-1 inherent.

Regarding '010, Applicants assert that '010 teaches the use of the polynucleotide and/or polypeptide compositions as immunogenic compositions (column 45, lines 13-15, column 78, lines 61-65; and column 79, lines 15-17). An immunogenic composition is a composition that produces immunity or evokes an immune response (See Dorland's Medical Dictionary, page 880). Still further, '010 states in column 45, lines 30-35

An "immunogenic portion", as used herein, is a fragment of an immunogenic polypeptide of the invention that itself is immunologically reactive (i.e., specifically binds) with the B-cells and/or T-cell surface antigen receptors that recognize the polypeptide.

Applicants assert that the purpose of '010 is not similar to the claims of the present invention. Although SEQ. ID. NO. 1825 may be similar to TREM-1 or SEQ. ID. NO. 1, the claims of the present invention are drawn to decreasing an immune response or myeloid cell activation by administering an inhibitor to the TREM-1 ligand resulting in a decrease in the activity of DAP12/TREM-1 complex. This is the opposite of '010 which teaches generation of an immune response using polypeptides, such as SEQ. ID. NO. 1825. Thus, '010 does not teach nor inherently teach the present invention.

If the Examiner continues to maintain a rejection that relies on inherency, Applicants respectfully request the Examiner to point to the page and line of '526 and/or '010 that justifies the rejection. See *Ex parte Schricker*, 56 USPQ2d 1723 (B.P.A.I. 2000).

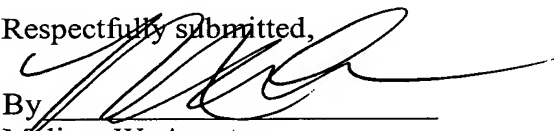
In view of the above arguments, Applicants respectfully request that the rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10023489 from which the undersigned is authorized to draw.

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Respectfully submitted,



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